

REMARKS

The final Office Action of April 8, 2010, has been received and reviewed.

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 and 59-88 were previously pending and under consideration in the above-referenced application. Each of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 and 59-88 has been rejected.

Reconsideration of the above-referenced application is respectfully requested.

Claim Objections

The Office has objected to claim 50, 53-57, and 59-78 for allegedly being substantial duplicates of claims 1, 4-8, 11, 12, 14-16 and 18.

It is respectfully submitted that none of independent claims 50, 68, or 72 is a substantial duplicate of independent claim 1.

The nutritional supplement of independent claim 50 lacks several elements of the nutritional supplement of independent claim 1: "at least one low density lipoprotein (LDL) receptor-binding component" and "at least one blood cholesterol reduction component." In view of the fact that the nutritional supplement of independent claim 50 lacks these two elements of the nutritional supplement of independent claim 1, it is respectfully submitted that independent claim 50 cannot be considered a substantial duplicate of independent claim 1.

Independent claim 68 is drawn to a nutritional supplement that includes several specific elements that are not necessarily required of the nutritional supplement of independent claim 1: "Vitamin C," "niacinamide," "an arginine-containing compound," and "a lysine-containing compound." As these elements are narrower than the corresponding elements recited by independent claim 1, independent claim 68 should not be considered to be a substantial duplicate of independent claim 1.

Independent claim 72 is directed to a composition that includes a first amount of a preparation that includes transfer factor and the first amount of vitamin C. The composition of independent claim 72 differs significantly in scope from the composition of independent claim 1, which does not specifically require vitamin C or that the vitamin C be present in the same

amount as the preparation that includes transfer factor, but does require a number of additional elements. Therefore, independent claim 72 is not a substantial duplicate of independent claim 1.

In view of the foregoing, withdrawal of the objections to claims 50, 53-57 and 59-78 is respectfully solicited.

Rejections under 35 U.S.C. § 112, Second Paragraph

The Office has rejected claim 62 under 35 U.S.C. §112, second paragraph, for being drawn to subject matter that is allegedly not definite. Specifically, the Office has asserted that "[i]t is vague whether a portion of the at least one antioxidant intends to claim that the structural portion of the antioxidant is present as a vitamin, a mineral and herb/plant extract, or that the antioxidant is part of the vitamin, the mineral and the herb/plant extract, or the antioxidant can be a vitamin, a mineral and a herb/plant extract." Final Office Action, page 3.

As proposed to be amended, claim 62 clearly recites that at least one of the "at least one vitamin, the at least one mineral, and the at least one herb or plant extract comprises the at least one antioxidant." From this recitation, it should be clear to one of ordinary skill in the art that claim 62 covers compositions in which the antioxidant is part of the at least one vitamin, the at least one mineral, or the at least one herb or plant extract, as well as compositions where the antioxidant is the at least one vitamin, the at least one mineral, or the at least one herb or plant extract.

It is, therefore, respectfully submitted that claim 62 is drawn to subject matter that complies with the definiteness requirement of the second paragraph of 35 U.S.C. § 112. Accordingly, withdrawal of the 35 U.S.C. § 112, second paragraph, rejection of claim 62 is respectfully solicited.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 59, 62-64 and 79-88 stand rejected under 35 U.S.C. § 112, first paragraph, for purportedly lacking an adequate written description in the as-filed specification.

In particular, claim 59 has been rejected for “introduc[ing] a new limitation of the at least one mineral comprising an LDL receptor-binding component.” As proposed to be amended, claim 59 recites that the at least one mineral “is part of” and LDL receptor-binding component. An embodiment of support for this recitation, magnesium lysinate, is provided at paragraphs [0023] and [0035] of the as-filed specification. One of ordinary skill in the art would recognize that magnesium is a mineral, and that magnesium (or ions thereof) is also part of magnesium lysinate, which is an embodiment of an LDL receptor-binding component.

Claim 62 has been rejected because the as-filed specification purportedly provides no adequate written description of at least one vitamin, at least one mineral, or at least one herb or plant extract that comprises at least one antioxidant. According to paragraph [0028] of the as-filed specification, beta carotene, vitamin A, and vitamin E are embodiments of vitamins that comprise antioxidants. Paragraph [0037] of the as-filed specification indicates that magnesium dehydroascorbic acid is an embodiment of a mineral that comprises an antioxidant. One of ordinary skill in the art would readily recognize that a large number of herb and plant extracts (e.g., orange extracts, grape extracts, etc.) also include antioxidants.

The composition of independent claim consists of (among a variety of other elements) “at least one source of transfer factor. Paragraph [0031] of the as-filed specification identifies the specific ingredients of an embodiment of a composition that falls within the scope of independent claim 79 that includes “at least one source of transfer factor:” “Transfer Factor (Cardio-TF-XFTM).”

It is proposed that independent claim 80 be amended to replace “at least one source of transfer factor” with “a source of transfer factor,” which also has support at paragraph [0031] of the as-filed specification.

As the original specification of the above-referenced application supports the subject matter recited by claims 59, 62, 79, and 80, it is respectfully submitted that each of these claims complies with the written description requirement of the first paragraph of 35 U.S.C. § 112.

The remaining claims were apparently included in the rejection for depending from one of claims 62 or 80 and, therefore, are allowable for the same reasons as claims 62 and 80.

Withdrawal of the 35 U.S.C. § 112, first paragraph, written description rejections of claims 59, 62-64 and 79-88 is, accordingly, respectfully requested, as is the allowance of each of these claims.

Rejections under 35 U.S.C. § 103(a)

Claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 and 59-78 are rejected under 35 U.S.C. § 103(a) for being drawn to subject matter that is purportedly not patentable over teachings from U.S. Patent 6,203,818 to Vester (hereinafter "Vester"), in view of teachings from Kirkpatrick, "Properties and Activities of Transfer Factor," J. Allergy & Clin. Immunol., 55(6):411-421 (1975) (Abstract) (hereinafter "Kirkpatrick"), Campbell et al., "Chlamydia pneumonia and Cardiovascular Disease", Emerging Infectious Diseases, 4(4):571-579 (1998) (hereinafter "Campbell"); U.S. Patent 6,506,413 to Rath et al. (hereinafter "Rath"), Tentolouris et al., "L-Arginine in coronary atherosclerosis," Int'l J. Cardiol., 75:123-128 (2000) (hereinafter "Tentolouris"); Kemper, Ginger (Zingiber officinale), Longwood Herbal Task Force: <http://www.mcp.edu/herbal/default.html> 1999, pp. 1-18 (hereinafter "Kemper"); and U.S. Patent 5,080,895 to Tokoro (hereinafter "Tokoro").

There are several requirements in establishing a *prima facie* case of obviousness against the claims of a patent application. All of the limitations of the claim must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Even then, a claim "is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). The Office must also establish that one of ordinary skill in the art would have had some reason to predict that the purported modification or combination of reference teachings would have been successful. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). There must also "be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.*, quoting *In re Kahn*, 441, F.3d 977, 988 (Fed. Cir. 2006). That reason must be found in the prior art, common knowledge, or derived from the nature of the problem itself, and not based on the Applicant's disclosure. *DyStar Textilfarben GmbH & Co.*

Deutschland KG v. C. H. Patrick Co., 464 F.3d 1356, 1367 (Fed. Cir. 2006). A mere conclusory statement that one of ordinary skill in the art would have been motivated to combine or modify reference teachings will not suffice. *KSR* at 1396.

It is respectfully submitted that the Office has not articulated any specific reason for one of ordinary skill in the art to have combined teachings from Vester, Kirkpatrick, Campbell, Rath, Tentolouris, Kemper, and Tokoro to develop a nutritional supplement that “consists of” all of the elements recited by any of independent claims 1, 50, or 68.

The teachings of Vester relate to nutritional supplements that include flavonoids (specifically quercetin) and folic acid for promoting cardiovascular health.

The teachings of Kirkpatrick relate to substantially pure transfer factor. The teachings of Kirkpatrick are limited to techniques for purifying transfer factor from other substances. By limiting its teachings to the purification of transfer factor, Kirkpatrick effectively teaches away from mixing transfer factor with other substances. *See* col. 3, line 28, to col. 4, line 12.

Campbell discusses the role of *Chlamydia pneumonia* in cardiovascular disease.

Rath teaches the use of lysine-based substances conjunction with antioxidants, such as ascorbic acid and tocopherols, to prevent and/or treat cardiovascular disease.

Tentolouris suggests that L-arginine may be used to treat subjects at risk for atherosclerosis.

The teachings of Kemper relate to the use of ginger in treating a variety of conditions, including high cholesterol.

The teachings of Tokoro are limited to a “transfer factor-like” substance that those of ordinary skill in the art recognize as something other than transfer factor. This is apparent for at least two reasons. First, Tokoro surmises that “[t]here is a possibility that a part of the transfer factor-like component is the same as the food factor described in [U.S. Patent 4,402,938 to Collins et al.]” (col. 7, lines 51-53), which has a molecular weight of no more than about 1,200 Da—much less than the lower end of the long-established molecular weight range for transfer factor. Second, Tokoro clearly teaches that “the immunological functions of the

transfer factor-like component... are not known.” Col. 7, lines 44-47. By November 25, 1985, when the Japanese predecessor of Tokoro was filed, however, those of ordinary skill in the art had a clear understanding of the immunological functions of transfer factor. *See, e.g.*, Dunnick, W., et al., “Lack of Antigen Fragments in Guinea Pig Transfer Factor-like Activity, Clin. Immunol. and Immunopathol. 17: 55-65 (1980) (which stresses the differences between transfer factor and a transfer factor-like component) (a copy of which is enclosed for the sake of convenience).

If one of ordinary skill in the art were to combine teachings from Vester, Kirkpatrick, Campbell, Rath, Tentolouris, Kemper, and Tokoro, as the Office has asserted, the resulting composition would include at least one element in addition to those recited by each of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 and 59-71—the “transfer factor-like” substance of Tokoro. Thus, the resulting composition would not meet the “consisting of” requirement of any of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 or 59-71.

Moreover, with respect to claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57 and 59-78, it is respectfully submitted that Kirkpatrick teaches away from combining its teachings with those of Vester, Campbell, Rath, Tentolouris, Kemper, and Tokoro in the manner that has been asserted. Specifically, Kirkpatrick teaches away from compositions that include transfer factor in addition to other ingredients, as such ingredients would apparently interfere with the characterization and stability of transfer factor. Col. 4, lines 49-64.

In addition, with respect to the subject matter recited by independent claims 1, 50, and 68 and, thus, by their dependent claims 4-8, 11, 12, 14-16, 18, 53-57, 59-67, and 69-71, it is respectfully submitted that none of Vester, Kirkpatrick, Campbell, Rath, Tentolouris, Kemper, or Tokoro appears to teach or suggest a composition that includes at least one mineral.

Moreover, while Campbell teaches that *Chlamydia pneumonia* causes acute respiratory disease, none of the references that have been relied upon in rejecting claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-78 teaches or suggests a composition that includes transfer factor that is specific for *Chlamydia pneumoniae*, cytomegalovirus, or *Heliobacter pylori*, as is required

of the compositions recited by independent claim 1, independent claim 50, and independent claim 68.

As for the subject matter to which independent claim 72 and its dependent claims 73-78 are drawn, none of Vester, Kirkpatrick, Campbell, Rath, Tentolouris, Kemper, or Tokoro, taken alone or in any combination, teaches or suggests a composition that includes a preparation including transfer factor and vitamin C *in the same amounts*.

The Office has asserted that it would have been *obvious* for one of ordinary skill in the art to *optimize* the amounts of the ingredients recited by independent claim 72. Office Action of September 24, 2009, page 14. Yet, none of the cited references teaches or suggests a composition that includes transfer factor and vitamin C in the same amounts. Nor has the Office identified anything in the art that indicates that a composition that includes transfer factor and vitamin C in the same amounts would have been predictable to one of ordinary skill in the art, as is required of each of the exemplary rationales set forth by M.P.E.P. § 2143 for establishing a *prima facie* case of obviousness.

Therefore, it is respectfully submitted that the Office has not established a *prima facie* case of obviousness against independent claim 72 or any of its dependent claims 73-78.

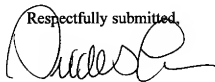
In view of the foregoing, it is respectfully submitted that the Office has not established a *prima facie* case of obviousness against any of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, or 59-78, as would be required to maintain the 35 U.S.C. § 103(a) rejections of these claims.

CONCLUSION

It is respectfully submitted that each of claims 1, 4-8, 11, 12, 14-16, 18, 50, 53-57, and 59-88 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be

resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



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